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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,383	02/19/2002	Jim C. Spain	AFD471	1410

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DEPARTMENT OF THE AIR FORCE  
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2240 B ST., RM. 100  
WRIGHT-PATTERSON AFB, OH 45433-7109

[REDACTED] EXAMINER

MARX, IRENE

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1651

DATE MAILED: 09/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/076,383	SPAIN ET AL.	
	Examiner Irene Marx	Art Unit 1651	
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>			
<b>Period for Reply</b>			
<b>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</b>			
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>			
<b>Status</b>			
1) <input type="checkbox"/> Responsive to communication(s) filed on _____.			
2a) <input type="checkbox"/> This action is <b>FINAL</b> .		2b) <input checked="" type="checkbox"/> This action is non-final.	
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
<b>Disposition of Claims</b>			
4) <input checked="" type="checkbox"/> Claim(s) <u>1-11</u> is/are pending in the application.			
4a) Of the above claim(s) _____ is/are withdrawn from consideration.			
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.			
6) <input checked="" type="checkbox"/> Claim(s) <u>1-11</u> is/are rejected.			
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.			
8) <input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.			
<b>Application Papers</b>			
9) <input type="checkbox"/> The specification is objected to by the Examiner.			
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.			
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
<b>Priority under 35 U.S.C. §§ 119 and 120</b>			
13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).			
a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.			
14) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.			
15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.			
<b>Attachment(s)</b>			
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .	
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)	
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> .		6) <input type="checkbox"/> Other: _____ .	

Art Unit: 1651

The application should be reviewed for errors

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 11 are vague and indefinite in the recitation of HabA and HabB. The complete designation of enzymes is required to clarify the invention.

Claims 4, 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to the use of enzymes expressed from cloned genes, wherein the enzymes in claim 4 are not identified as to source and claims 10 and 11 pertain to specific enzymes. In contrast, the specification only provides guidance for the use of a partially purified cloned enzyme originating from *P. pseudoalcaligenes* JS45. No guidance is presented for the identification, isolation, cloning and expression of enzymes for the process of using unidentified enzymes or for the process of claims 10 and 11. Moreover, from Davis *et al.* it is apparent that the regulation of expression of these genes at least in *E. coli* is unpredictable. (See, e.g., page 2969). Moreover, the specificity of these enzymes with respect to the production of any *ortho*-aminophenol from any nitroarene is not disclosed in the instant written disclosure.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the claimed invention.

See University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Art Unit: 1651

See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene (or promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence), and at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

### ***Rejections under 35 U.S.C § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel *P. pseudoalcaligenes* JS45. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It is not clear if the deposit meeting all of the criteria set forth in 37 CFR 1.801-1.809 is available. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

### **SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL**

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Art Unit: 1651

5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Davis *et al.*.

The claims are directed to the biotransformation of nitroarenes into ortho-aminophenols using a nitroreductase and a mutase, preferably from *P. alcaligenes* JS45.

The reference discloses the biotransformation of nitroarenes into ortho-aminophenols using a nitroreductase and a mutase from *P. alcaligenes* JS45 (See, e.g., page 2966).

Art Unit: 1651

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nishino *et al.*.

The claims are directed to the biotransformation of nitroarenes into ortho-aminophenols using a nitroreductase and a mutase, preferably from *P. alcaligenes* JS45.

The reference discloses the biotransformation of nitroarenes into ortho-aminophenols using a nitroreductase and a mutase from *P. alcaligenes* JS45 (See, e.g., page 2522).

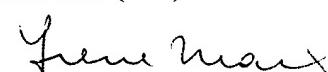
Claims 4 and 8-11 are free of the art of record.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



Irene Marx  
Primary Examiner  
Art Unit 1651